IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	**Case No. 1:26-cv-00431 (CJN)**

DECLARATION OF DALIA A. MAHMOUD

I, Dalia A. Mahmoud, pursuant to 28 U.S.C. § 1746, declare as follows:

I. Introduction

1. I am Vice President for U.S. Inflation Reduction Act (IRA) Strategy and Most Favored Nation Commercial Execution at AbbVie Inc. My job responsibilities include leading AbbVie's engagement with the Centers for Medicare & Medicaid Services (CMS) regarding products selected for the Medicare Drug Price Negotiation Program (the Program). I have also held leadership roles at AbbVie in global market access and pricing as well as commercial operations. I have personal knowledge of the facts stated herein through my work and my review of AbbVie's business records and correspondence with regulatory agencies. I submit this declaration in support of AbbVie's motion for summary judgment.

2. AbbVie works to discover and manufacture innovative medicines that solve the most pressing medical needs of today and tomorrow. AbbVie's products have therapeutic uses across numerous fields, including immunology, oncology, neuroscience,

and eyecare. AbbVie annually invests billions of dollars into the research and development of new medicines, and its products treat 16 million Americans annually.

3. AbbVie manufactures and sells BOTOX®, a biological product with twelve FDA therapeutic indications across eight chronic and debilitating diseases spanning adult and pediatric populations, including chronic migraine, spasticity, overactive bladder, cervical dystonia, and neurogenic detrusor overactivity. BOTOX Cosmetic® is licensed for four cosmetic indications. Although BOTOX's therapeutic indications are covered under Medicare and Medicaid, its cosmetic indications are not.

4. I have reviewed the regulatory history of BOTOX and am familiar with AbbVie's operations more generally. In addition, I have personal knowledge of BOTOX's financial profile, including associated revenues and research and development costs. I also have personal knowledge of the structure and operation of the Program under the terms of the Inflation Reduction Act of 2022 (IRA) and guidance from the CMS, an agency within the Department of Health and Human Services (HHS).

II. AbbVie's Participation In Medicare And Medicaid

5. Medicare and Medicaid provide health insurance to more than 100 million eligible Americans and account for almost 40% of the U.S. health-care market and 45% of prescription-drug spending. Medicare offers prescription drug coverage, including through Medicare Parts B and D, which cover provider-administered drugs and self-administered prescription drugs, respectively. States operate Medicaid, and each state plan provides coverage for outpatient prescription drugs.

6. Before the enactment of the IRA, market-based indicators largely dictated drug prices under Medicare and Medicaid. Under Medicaid, manufacturers must pay

rebates calculated based on market-based indicators, such as average manufacturer price and best price. *See* 42 U.S.C. § 1396r-8(c). Prices for drugs covered by Medicare Part B have long been determined by a formula based on a drug's average sales price. 42 U.S.C. § 1395w-3a. And prices for drugs covered by Part D have been negotiated by manufacturers and private insurers or their private plan sponsors. 42 U.S.C. § 1395w-111(d)(2), (i). Congress prohibited CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [private plan] sponsors" with respect to Part D drug prices or "institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1), (3).

7. AbbVie has participated in Medicare and the Medicaid Drug Rebate Program since 2013. In order for its products to be covered under Medicare Part B, AbbVie must enter into rebate agreements with each approved state Medicaid plan. *See* 42 U.S.C. § 1396r-8(a)(1). For coverage under Medicare Part D, AbbVie must enter into separate agreements. *See* 42 U.S.C. § 1395w-153(a).

8. AbbVie receives payment for dozens of different drugs, including BOTOX, that are prescribed to Medicare and Medicaid beneficiaries. Those drugs include life-saving and other critical medicines not available from other manufacturers. In 2025, approximately [redacted] Medicare and Medicaid beneficiaries filled approximately [redacted] prescriptions for drugs manufactured by AbbVie. In 2025, those sales accounted for approximately [redacted], representing [redacted] of the company's gross sales, and for [redacted] of AbbVie's net pharmaceutical revenue, representing [redacted] of the company's net pharmaceutical revenue.

9. Because Medicare and Medicaid sales constitute a very large portion of both the U.S. pharmaceutical market and AbbVie's business, AbbVie's ability to participate in these markets is critical to its mission to discover and deliver innovative medicines and life-saving solutions.

III. The Program

10. The IRA disrupted this landscape through its establishment of the Program. As relevant here, the IRA requires CMS to "negotiate" prices—i.e., set the prices to be paid by Medicare and Medicaid—on certain drugs and biological products. *See* 42 U.S.C. § 1320f(a)(3). By February 1 two years before the new, government-mandated price takes effect, CMS must "select" between 10 and 20 new "negotiation-eligible drugs" each year for "negotiation," with eligible drugs selected from among other "qualifying single source drugs" based on their contribution to Medicare drug spending. *See* 42 U.S.C. §§ 1320f(b)(3), 1320f-1(a), (b).

11. The IRA provides that certain categories of drugs or biological products that would otherwise be "qualifying single source drugs" are ineligible for selection. One such exclusion provides that CMS may not select for "negotiation" "[p]lasma-derived products," that is, "biological product[s] that [are] derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). That exclusion recognizes that manufacturers of plasma-derived products are especially vulnerable to shocks to the supply of donated blood and plasma. These supply-chain risks are not hypothetical. For example, during the COVID-19 pandemic, fewer people visited plasma-collection centers, and the supply of donated plasma contracted sharply.

12. After CMS publishes its list of selected drugs, manufacturers have until February 28 of that year to "enter into agreements" with CMS, and those "agreements" require manufacturers to "agree" to "negotiate to determine" a "maximum fair price." 42 U.S.C. § 1320f-2(a)(1). CMS has published a template Medicare Drug Price Negotiation Agreement that is sent to a manufacturer when its drug is selected for the Program. *See* CMS, Medicare Drug Price Negotiation Program Agreement, <https://tinyurl.com/ManufacturerAgreementTemplate> (Template Program Agreement). I have reviewed and am familiar with this document.

13. The first step in this "negotiation" is for a manufacturer to sign CMS's form manufacturing agreement. According to this agreement, each affected manufacturer must express that it "agree[s]" that it will "negotiate to determine" and ultimately "agree to" a "maximum fair price." Template Program Agreement at 2. A manufacturer that violates any term of its agreement with CMS will face a statutory civil monetary penalty of $1 million per day. *See* 42 U.S.C. § 1320f-6(c).

14. After entering this "agreement," the manufacturer must engage in a "negotiation" in which it must accept whatever price CMS ultimately sets. By June 1 of the selection year, CMS must provide the manufacturer with an "initial offer" along with a "concise justification." 42 U.S.C. § 1320f-3(b)(2)(B). Within 30 days of receiving CMS's opening offer, the manufacturer must either accept that offer or "counteroffer." 42 U.S.C. § 1320f-3(b)(2)(C). CMS must "respond in writing" to the counteroffer, but the IRA does not require it to negotiate any further with the manufacturer. *See* 42 U.S.C. § 1320f-3(b)(2)(D). In making an offer, CMS must set the "maximum fair price" no higher than the ceiling price. 42 U.S.C. § 1320f-3(b)(2)(F)(i). The IRA requires the "maximum fair

price" for a "[l]ong-monopoly drug" to be set at no more than 40% of the drug's private-market wholesale price. *See* 42 U.S.C. § 1320f-3 (c)(3)(C), (c)(5).

15. A manufacturer whose product is selected but who does not wish to engage in the price-setting process may decline either the initial offer to "negotiate" or CMS's final offer on a "maximum fair price." If a manufacturer refuses, however, it must pay an escalating daily excise tax that starts at 186% and increases to 1,900% of the product's daily sales. 26 U.S.C. § 5000D(a), (d). Alternatively, the manufacturer could withdraw *all* of its products—not just the selected drug—from both Medicare and Medicaid. 26 U.S.C. § 5000D(c); CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, at 257-259 & n.148 (2025) (IPAY 2028 Guidance). This "option," however, exists only in theory. By statute, voluntary manufacturer withdrawals from Medicare and Medicaid programs take 11 to 23 months. *See* 42 U.S.C. §§ 1396r-8(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). That presents a problem because the IRA affords manufacturers only approximately one month to decide whether to "negotiate" before the IRA's excise taxes kick in. If a manufacturer decides to opt out of "negotiations" through the withdrawal option, the IRA instructs that the manufacturer will remain subject to penalties until withdrawal is complete.

IV. Pre-Selection Discussions And AbbVie's Participation In The Program

16. In 2025, AbbVie's internal projections suggested that, if not for the IRA's express exclusion for plasma-derived products, CMS might select BOTOX for the Program based on its proposed methodology for calculating Medicare Part B and D expenditures.

At that point, to the best of AbbVie's knowledge, CMS had not yet had occasion to apply the IRA's exclusion for plasma-derived products, and AbbVie sought to ensure CMS applied the exclusion properly and did not improperly select BOTOX. As a plasma-derived product, BOTOX is vulnerable to the kinds of supply-chain disruptions that affect plasma-derived products generally.

17. To underscore BOTOX's ineligibility for selection, on October 16, 2025, AbbVie sent a letter to CMS requesting a meeting to discuss why BOTOX satisfies the IRA's plasma-derived-products exclusion. In that letter, AbbVie explained that BOTOX contains Human Serum Albumin (HSA), which comes from whole blood collected from human donors, and is thus "derived from human whole blood or plasma" within the plain text of the plasma-derived-products exclusion.

18. On November 26, 2025, AbbVie met with the Deputy General Counsel in the HHS Office of the General Counsel and the Chief Legal Officer for CMS to reiterate why BOTOX is subject to the plasma-derived-products exclusion and therefore is ineligible for selection for the Program. After the meeting, AbbVie and CMS continued to engage in email correspondence until January 8, 2026. Attached hereto as **Exhibit 1** is a true and correct copy of the email correspondence between AbbVie and CMS from October 16, 2025 through January 8, 2026. I have reviewed these communications and am familiar with their contents.

19. On December 5, 2025, AbbVie provided CMS additional materials, including a letter from Dr. Andrew Pickett about the important role that HSA plays in BOTOX and a declaration from Dr. Martin Gastens about AbbVie's dependence on the HSA supply chain.

20. On December 9, 2025, AbbVie met with Chris Klomp, Director of Medicare and Deputy Administrator of CMS, for further discussions about BOTOX. After the meeting, AbbVie requested a follow-up phone call to clarify any misconceptions about the application of the IRA's exclusion for plasma-derived products and the role HSA plays in BOTOX. *See* Ex. 1 at 3-4. CMS did not respond directly to the request for a follow-up meeting but asked AbbVie to send any additional materials in writing. *Id*. at 2-3.

21. On January 8, 2026, AbbVie sent a follow-up e-mail and letter to CMS reiterating why, under a plain reading of the IRA's text, BOTOX is subject to the plasma-derived-products exclusion. *See id*. at 1. In that letter, AbbVie underscored that HSA plays an integral role in achieving BOTOX's intended effects. Attached hereto as **Exhibit 2** is a true and correct copy of AbbVie's January 8, 2026 letter to CMS. I have reviewed this document and am familiar with its contents.

22. CMS never refuted AbbVie's view. And, despite these multiple points of contact, CMS provided no feedback as to how it would apply the plasma-derived products exclusion to BOTOX.

23. CMS selected BOTOX as part of the Program on January 27, 2026. It offered no explanation for why BOTOX was selected. Attached hereto as **Exhibit 3** is a true and correct copy of CMS's official notice of BOTOX's selection under the Program. I have reviewed this document and am familiar with its contents.

24. If AbbVie refused to "negotiate," it would have been subject to a crippling daily penalty beginning at 186% and escalating to 1,900% of BOTOX's daily sales.

[redacted]

[redacted] AbbVie could not pay those taxes without endangering its financial viability.

25. Moreover, the withdrawal of AbbVie's products from Medicare and Medicaid was impossible for multiple independent reasons. Given that BOTOX was selected on January 27, 2026, AbbVie would have been required to withdraw all of its products—not just BOTOX—from Medicare and Medicaid by March 1 to avoid penalties. That was an insufficient amount of time for AbbVie to comply with the statutorily prescribed withdrawal timeline, which imposes various delay periods between when a manufacturer files a notice of its withdrawal and when that withdrawal becomes effective. *See* 42 U.S.C. §§ 1396r-8(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii).

26. Even if the statutory delay period did not exist, AbbVie would have had, at most, approximately 30 days to decide whether to remove its products from Medicare and Medicaid altogether. That is practically impossible. As noted, in 2025, prescriptions filled by Medicare and Medicaid beneficiaries accounted for [redacted], representing [redacted] of the company's gross sales, and [redacted] of AbbVie's net pharmaceutical revenue, representing [redacted] of the company's net pharmaceutical revenue. Those resources are critical and enable AbbVie to maintain its manufacturing and safety standards and develop critical, life-saving technologies. What is more, forcing AbbVie to hastily withdraw all of its products from Medicare and Medicaid would leave millions of Medicare and Medicaid patients without coverage for drugs they rely upon to treat various

conditions, including life-threatening diseases, and impair AbbVie's reputation and relationships with providers.

27. Despite its belief that BOTOX is ineligible for selection, AbbVie did not believe it had any other choice but to "negotiate" due to the legal, practical, and economic infeasibility of withdrawal. As such, on February 25, 2026, AbbVie signed a "Medicare Drug Price Negotiation Program Agreement" (Agreement) drafted by CMS. Attached hereto as **Exhibit 4** is a true and correct copy of the Agreement signed by AbbVie. I have reviewed this document and am familiar with its contents.

28. The Agreement states, among other things, that "CMS and [AbbVie] agree" that they "shall negotiate to determine" and "agree to[] a maximum fair price" for BOTOX. Ex. 4 at 1-2.

29. AbbVie rejects the views expressed in the Agreement. AbbVie does not believe that the Program is a bona fide "negotiat[ion]," because AbbVie is not free to walk away from the negotiations entirely and because CMS has unilateral authority to set a price so long as that price falls below the statutory "ceiling price." Similarly, AbbVie does not believe that it has "agree[d]" to "negotiate" a price for BOTOX, as AbbVie entered the Program only under threat of excise taxes and penalties. Finally, AbbVie rejects that the "maximum fair price" that will be imposed by CMS is "fair." Instead, AbbVie believes that its current market-based pricing models, which allow AbbVie to deliver high-quality, accessible care while continuing to innovate, are fair to all its stakeholders—patients, providers, and payors included.

V. The Effects Of The Program

30. I anticipate that the selection of BOTOX for the Program will reduce realized prices and revenues for Medicare-covered uses of BOTOX. At the time of the passage of the IRA, the Congressional Budget Office estimated that "net prices for selected drugs will decrease by roughly 50 percent, on average, as a result of negotiation."[1] Additionally, the IRA requires CMS to set the maximum fair price no higher than a drug's "[c]eiling" price, which is calculated using a specified formula. *See* 42 U.S.C. § 1320f-3(c). Because BOTOX qualifies as a "long-monopoly drug" under that formula, the maximum fair price for the drug is required to be *at least* 60% lower than the drug's "average non-Federal average manufacturer price" (to simplify, its wholesale price). 42 U.S.C. § 1320f-3(c)(1)(C), (3)(C). [redacted] price, that would correspond to a loss of revenue of approximately [redacted] through 2035.

31. The imposition of price controls on BOTOX will also affect BOTOX's performance on non-Medicare markets. [redacted] *See* 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(V) (expressly defining "best price" used for Medicaid rebate calculations to include the maximum fair price).

[1] Congressional Budget Office, How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act 10 (2023), https://tinyurl.com/IRA-CBO-Estimate.

32. These revenue reductions would directly and negatively affect AbbVie's ability to sustain the specialized compliance, sourcing, and manufacturing systems required by BOTOX's plasma-derived HSA component. Maintaining qualified HSA suppliers, executing long-lead procurement and safety-stock strategies, and funding continued process control improvements, analytical enhancements, and regulatory commitments all depend on predictable cash flows. Selection-driven price cuts would constrain these activities and increase the risk of supply disruptions if supplier variability or donation shocks occur.

33. Reduced revenues would also impair AbbVie's allocation of capital to ongoing research and development and to domestic manufacturing. As a manufacturer of branded pharmaceuticals, AbbVie invests heavily in discovering new medicines and in researching how existing medicines can also be used to treat other conditions. AbbVie currently has [redacted] research and development centers and more than 90 compounds, devices, or indications in development individually or under collaboration or license. In 2024, AbbVie spent more than $10 billion on research and development efforts. AbbVie relies on its ability to commercialize its medicines—including through sales of drugs for administration to Medicare and Medicaid beneficiaries—to fund research and development into the next generation of medicines and indications. Regarding BOTOX in particular, AbbVie recently invested $69 million in related domestic research and development capabilities to manage the scientific, security, and regulatory demands of its portfolio. The imposition of price controls will reduce cash flows derived from BOTOX, which will in turn decrease AbbVie's incentive to maintain sustained investment in related research moving forward.

34. Based on my experience, the combined effect of price controls, reimbursement compression, and the impact on pricing in other channels would be to diminish resources available for the specialized manufacturing and compliance systems that BOTOX requires as a plasma-derived biological product, and these effects would introduce new risks to supply continuity and patient access.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 04/28/2026

Dalia A. Mahmoud

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:26-cv-00431 (CJN)

INDEX OF EXHIBITS TO DECLARATION OF DALIA A. MAHMOUD IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Exhibit 1	Correspondence between Johanna Corbin, Senior Vice President, Chief Patent and Innovation Counsel, AbbVie Inc., and Beth Kelley, Acting Deputy General Counsel, Department of Health and Human Services (Oct. 16, 2025–Jan. 8, 2026).
Exhibit 2 (REDACTED)	Letter from Johanna Corbin, Senior Vice President, Chief Patent and Innovation Counsel, AbbVie Inc., to Beth Kelley, Chief Legal Officer, Centers for Medicare and Medicaid Services (Jan. 8, 2026).
Exhibit 3	Press Release, Centers for Medicare and Medicaid Services, CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program, Including First-Ever Part B Drugs (Jan. 27, 2026).
Exhibit 4	Medicare Drug Price Negotiation Program Agreement between AbbVie, Inc. and Centers for Medicare and Medicaid Services (Feb. 26, 2026).

EXHIBIT 1 to Mahmoud Declaration

From:	Corbin, Johanna M
To:	Kelley, Elizabeth (HHS/OGC)
Cc:	Pelovitz, Betsy (HHS/OGC); Drissel, Danielle M. (OS/OGC); Balke, Patrick (HHS/OGC); Lin, Trang H; Bownas, Pearson N; Stuart, Mike (HHS/OGC); Barr, Courtney E
Subject:	RE: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product
Date:	Thursday, January 8, 2026 11:47:51 AM
Attachments:	Confidential AbbVie Botox Letter to E. Kelley (Jan 8, 2026).pdf

Good afternoon Beth,

Thank you for your response. I appreciate the opportunity to provide a written response to supplement the materials AbbVie has provided to you and CMS to date, but I would like to reiterate our request for a meeting.

As this is likely the first instance in which CMS will apply the plasma-derived product exclusion under the IRA, it is essential that CMS follow the plain language of the law. BOTOX clearly qualifies for the exclusion under the statute. Even if CMS were to adopt an approach that considers the function of the plasma-derived ingredient, BOTOX would still qualify for the exclusion since HSA is pharmacologically active in BOTOX. Frankly, from my perspective, based on the science and the regulatory record, the HSA in BOTOX is an active component directly impacting the potency and activity of onabotulinumtoxinA. To that end, we aim to ensure that CMS has the information it needs regarding the underlying science and corresponding regulatory and manufacturing record for BOTOX®.

Enclosed please find a letter addressing these issues.

We remain optimistic that CMS will recognize that BOTOX is exempt from selection because it is a plasma-derived product.

Please let me know if you will reconsider meeting with us.

Sincerely,

Johanna

JOHANNA CORBIN
Senior Vice President, Chief Patent and Innovation Counsel
Intellectual Property, Transactions, and Innovation

AbbVie
AP34-2, Dept VPGP
1 North Waukegan Road
North Chicago, IL
60064
USA
OFFICE +1 847-935-7956
CELL +1 847-347-0398
EMAIL johanna.corbin@abbvie.com

abbvie.com

From: Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>
Sent: Monday, December 29, 2025 8:26 AM
To: Corbin, Johanna M <johanna.corbin@abbvie.com>; Barr, Courtney E <courtney.barr@abbvie.com>; Stuart, Mike (HHS/OGC) <Mike.Stuart@hhs.gov>
Cc: Pelovitz, Betsy (HHS/OGC) <Betsy.Pelovitz@hhs.gov>; Drissel, Danielle M. (OS/OGC) <Danielle.Drissel@hhs.gov>; Balke, Patrick (HHS/OGC) <Patrick.Balke@hhs.gov>; Lin, Trang H <trang.lin@abbvie.com>; Bownas, Pearson N <pearson.bownas@abbvie.com>; Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>
Subject: [EXTERNAL] RE: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product

Good morning Johanna,

I hope you enjoyed some time off last week. Thank you for your outreach regarding AbbVie's position on BOTOX and the plasma-derived product exclusion under the Medicare Drug Price Negotiation

Program. I appreciated your November 26 presentation and discussion with my team and me. I'm pleased your clients report that their December 9 meeting with the CMS team on this issue was engaging and productive as well. If you or Mr. Bownas have information that you would like to clarify or emphasize, please do so in writing at your earliest convenience.

Thanks,
Beth

Beth C. Kelley
Chief Legal Officer for CMS | Office of the General Counsel
U.S. Department of Health and Human Services
Elizabeth.Kelley@hhs.gov
(202) 815-8624 (cell)

From: Corbin, Johanna M <johanna.corbin@abbvie.com>
Sent: Tuesday, December 16, 2025 6:31 PM
To: Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>; Barr, Courtney E <courtney.barr@abbvie.com>; Stuart, Mike (HHS/OGC) <Mike.Stuart@hhs.gov>; Alvarado Diaz, Karla Maria (HHS/OGC) <Karla.AlvaradoDiaz@hhs.gov>
Cc: Pelovitz, Betsy (HHS/OGC) <Betsy.Pelovitz@hhs.gov>; Drissel, Danielle M. (OS/OGC) <Danielle.Drissel@hhs.gov>; Balke, Patrick (HHS/OGC) <Patrick.Balke@hhs.gov>; Lin, Trang H <trang.lin@abbvie.com>; Bownas, Pearson N <pearson.bownas@abbvie.com>
Subject: RE: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product

Good evening Beth,

We understand from our clients that last Tuesday's meeting was engaging and productive and again, I really appreciate the open dialogue between our two legal teams.

Would you and your team have availability this week or next week for a short call? We understand that in Tuesday's meeting, there were some inquiries about the definition of biological product and the plasma component of BOTOX. It is critical to us that our information is clear and understood by the CMS team. We believe the science and the regulatory record strongly support BOTOX falling within the exception. And while I hope that we agree, I would like to include my colleague, Pearson Bownas, the head of our litigation department, on our call.

I look forward to hearing from you.

Sincerely, Johanna

JOHANNA CORBIN
Senior Vice President, Chief Patent and Innovation Counsel
Intellectual Property, Transactions, and Innovation

AbbVie
AP34-2, Dept VPGP
1 North Waukegan Road
North Chicago, IL
60064
USA
OFFICE +1 847-935-7956
CELL +1 847-347-0398
EMAIL johanna.corbin@abbvie.com

abbvie.com

From: Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>
Sent: Sunday, December 7, 2025 11:12 AM

To: Corbin, Johanna M <johanna.corbin@abbvie.com>; Barr, Courtney E <courtney.barr@abbvie.com>; Stuart, Mike (HHS/OGC) <Mike.Stuart@hhs.gov>; Alvarado Diaz, Karla Maria (HHS/OGC) <Karla.AlvaradoDiaz@hhs.gov>
Cc: Pelovitz, Betsy (HHS/OGC) <Betsy.Pelovitz@hhs.gov>; Drissel, Danielle M. (OS/OGC) <Danielle.Drissel@hhs.gov>; Balke, Patrick (HHS/OGC) <Patrick.Balke@hhs.gov>; Lin, Trang H <trang.lin@abbvie.com>
Subject: [EXTERNAL] RE: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product

Johanna,

Thank you for the additional information. We appreciated your presentation and look forward to continuing the discussion.

Beth

Beth C. Kelley
Chief Legal Officer for CMS | Office of the General Counsel
U.S. Department of Health and Human Services
Elizabeth.Kelley@hhs.gov
(202) 815-8624 (cell)

From: Corbin, Johanna M <johanna.corbin@abbvie.com>
Sent: Friday, December 5, 2025 1:58 PM
To: Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>; Barr, Courtney E <courtney.barr@abbvie.com>; Stuart, Mike (HHS/OGC) <Mike.Stuart@hhs.gov>; Alvarado Diaz, Karla Maria (HHS/OGC) <Karla.AlvaradoDiaz@hhs.gov>
Cc: Pelovitz, Betsy (HHS/OGC) <Betsy.Pelovitz@hhs.gov>; Drissel, Danielle M. (OS/OGC) <Danielle.Drissel@hhs.gov>; Balke, Patrick (HHS/OGC) <Patrick.Balke@hhs.gov>; Lin, Trang H <trang.lin@abbvie.com>
Subject: RE: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product

Good afternoon, Beth,

Thank you for meeting on November 26. Since there were questions about the plasma-derived Human Serum Albumin (HSA) in BOTOX, we wanted to provide additional background about the unique relationship between onabotulinumtoxinA (onabotA) and HSA.

First, is a declaration from Dr. Andrew Pickett, an expert with over 40 years of experience in the toxin field. A copy of Dr. Pickett's CV is included after his declaration.

Second, is a declaration from Dr. Martin Gastens, the AbbVie senior scientist responsible for overseeing BOTOX manufacturing and supply.

We appreciate the opportunity to engage with you about the uniqueness of BOTOX and are happy to provide any additional information. We will also share these materials with the CMS attendees for the upcoming December 9 meeting.

Have a great weekend.

Sincerely,
Johanna

JOHANNA CORBIN
Senior Vice President, Chief Patent and Innovation Counsel
Intellectual Property, Transactions, and Innovation

AbbVie
AP34-2, Dept VPGP
1 North Waukegan Road
North Chicago, IL
60064
USA
OFFICE +1 847-935-7956

CELL +1 847-347-0398
EMAIL johanna.corbin@abbvie.com

abbvie.com

From: Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>
Sent: Friday, November 21, 2025 8:54 AM
To: Corbin, Johanna M <johanna.corbin@abbvie.com>; Barr, Courtney E <courtney.barr@abbvie.com>; Stuart, Mike (HHS/OGC) <Mike.Stuart@hhs.gov>; Alvarado Diaz, Karla Maria (HHS/OGC) <Karla.AlvaradoDiaz@hhs.gov>
Cc: Pelovitz, Betsy (HHS/OGC) <Betsy.Pelovitz@hhs.gov>; Drissel, Danielle M. (OS/OGC) <Danielle.Drissel@hhs.gov>; Balke, Patrick (HHS/OGC) <Patrick.Balke@hhs.gov>
Subject: [EXTERNAL] RE: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product

Good morning, Johanna,

I would be happy to meet to discuss this issue. I'm also copying two of my colleagues, Danielle Drissel and Patrick Balke, who will attend as well.

Karla (@Alvarado Diaz, Karla Maria (HHS/OGC)) – will you please find a time that would work for this group to meet?

Best,
Beth

Beth C. Kelley
Chief Legal Officer for CMS | Office of the General Counsel
U.S. Department of Health and Human Services
Elizabeth.Kelley@hhs.gov
(202) 815-8624 (cell)

From: Corbin, Johanna M <johanna.corbin@abbvie.com>
Sent: Thursday, November 20, 2025 5:16 PM

To: Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>; Barr, Courtney E <courtney.barr@abbvie.com>; Stuart, Mike (HHS/OGC) <Mike.Stuart@hhs.gov>
Cc: Pelovitz, Betsy (HHS/OGC) <Betsy.Pelovitz@hhs.gov>
Subject: RE: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product

Good evening Mr. Stuart and Ms. Kelley,

I am writing to re-engage with you on our October 16 letter now that the government has reopened and in anticipation of a meeting between our respective clients on December 9.

Upon receiving your email below and with the uncertainty around the duration of the government shutdown, AbbVie's CEO reached out to Chris Klomp to meet and discuss Botox's exclusion from IRA. Mr. Klomp agreed to meet with our CEO and two members of our executive leadership team on December 9. We thought it would be beneficial to connect, legal-to-legal, in anticipation of that meeting. If you agree, please let us know your availability.

Sincerely,
Johanna

JOHANNA CORBIN
Senior Vice President, Chief Patent and Innovation Counsel
Intellectual Property, Transactions, and Innovation

AbbVie
AP34-2, Dept VPGP
1 North Waukegan Road
North Chicago, IL

60064
USA
OFFICE +1 847-935-7956
CELL +1 847-347-0398
EMAIL johanna.corbin@abbvie.com

abbvie.com

From: Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>
Sent: Thursday, October 16, 2025 5:14 PM
To: Barr, Courtney E <courtney.barr@abbvie.com>; Stuart, Mike (HHS/OGC) <Mike.Stuart@hhs.gov>
Cc: Pelovitz, Betsy (HHS/OGC) <Betsy.Pelovitz@hhs.gov>; Corbin, Johanna M <johanna.corbin@abbvie.com>
Subject: [EXTERNAL] RE: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product

Good evening, Ms. Barr,

Thank you for your letter. Unfortunately, during the government shutdown, we are not permitted to meet.

Thanks,
Beth

Beth C. Kelley
Chief Legal Officer for CMS | Office of the General Counsel
U.S. Department of Health and Human Services
Elizabeth.Kelley@hhs.gov
(202) 815-8624 (cell)

From: Barr, Courtney E <courtney.barr@abbvie.com>
Sent: Thursday, October 16, 2025 3:54 PM
To: Stuart, Mike (HHS/OGC) <Mike.Stuart@hhs.gov>; Kelley, Elizabeth (HHS/OGC) <Elizabeth.Kelley@hhs.gov>
Cc: Pelovitz, Betsy (HHS/OGC) <Betsy.Pelovitz@hhs.gov>; Corbin, Johanna M

<johanna.corbin@abbvie.com>

Subject: Inflation Reduction Act: Exclusion of BOTOX® (onabotulinumtoxinA) as a plasma-derived biological product

Dear Mr. Stuart and Ms. Kelley,

Please see attached letter requesting a meeting with you to more fully discuss and explain why BOTOX® (onabotulinumtoxinA) is not subject to price controls under the "Medicare Drug Price Negotiation Program" provisions of the Inflation Reduction Act of 2022 (IRA) because it falls within the plasma-derived exclusion under section 1192(e)(3)(C) of the IRA.

We request a meeting between AbbVie and CMS before October 31, 2025, to discuss BOTOX's status and any questions you may have.

We understand Mr. Stuart was recently sworn in as General Counsel of the Department of Health and Human Services. If this is not his correct email address, please kindly forward this correspondence to him.

Sincerely,

Courtney E. Barr on behalf of Johanna M. Corbin

COURTNEY E. BARR
Vice President
R&D Innovation and Global Alliances Legal

AbbVie Inc.
Intellectual Property, Transactions, and Innovation Legal Dept.
1 N. Waukegan Rd., Dept. V377
AP34-2
North Chicago, IL 60064
OFFICE (+1) 847-936-8274
WORK CELL (+1) 847-643-6414
EMAIL courtney.barr@abbvie.com
abbvie.com

EXHIBIT 2 to Mahmoud Declaration (REDACTED)

abbvie

CONTAINS COMMERCIALLY CONFIDENTIAL INFORMATION
NOT SUBJECT TO FOIA; PRE-DISCLOSURE NOTIFICATION REQUIRED

January 8, 2026

BY EMAIL

Beth C. Kelley
Chief Legal Officer for CMS, Office of the General Counsel
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, D.C. 20201
elizabeth.kelley@hhs.gov

Dear Ms. Kelley,

I am writing in response to CMS's December 29, 2025 request that AbbVie submit in writing further thoughts regarding the exclusion of BOTOX® from the Medicare Drug Price Negotiation Program (Program) under the Inflation Reduction Act (IRA) because it is a plasma-derived product, as described in section 1192(e)(3)(C) of the Social Security Act (SSA), 42 U.S.C. § 1320f-1(e)(3)(C). This letter supplements AbbVie's prior letter to you dated October 16, 2025 (October 16 AbbVie Letter) and expert declarations submitted to you on December 5, 2025.

To briefly recap AbbVie's previously submitted materials:

- BOTOX falls within the plain language of the IRA's plasma-derived product exclusion because it is indisputably derived from human plasma.

- Human Serum Albumin (HSA) is an integral component of BOTOX, making up more than 1/3 of its physical composition and impacting BOTOX's clinical characteristics by increasing the binding activity of onabotulinumtoxinA (onabotA), affecting onabotA peak effect and duration, and increasing onabotA toxin availability within the injected muscle. The important relationship between botulinum neurotoxins and HSA is recognized in peer-reviewed literature and supported by our scientific data.

- Our FDA record illustrates that even small changes to HSA can, and have, materially impacted BOTOX. [redacted]

- The manufacture and availability of BOTOX are reliant on an adequate supply of appropriately qualified HSA. The integral role of HSA is well documented in BOTOX's United States Prescribing Information (USPI) and in our manufacturing and quality

abbvie

documentation, and it is further evidenced by the laws and regulations we must follow to source plasma from American donors for use in manufacturing BOTOX.

Notwithstanding significant public interest and stakeholders' multiple requests for comments over three rounds of IPAY guidance, CMS has declined to provide detailed guidance on how CMS intends on implementing the plasma-derived product exclusion. In light of this lack of guidance, AbbVie has sought to engage with you and CMS to encourage the agency to apply the exclusion in a manner that complies with the plain language of the statute and is fair, scientifically reasonable, and consistent. AbbVie submits this letter to elaborate on the following points:

- Under the plain text of the statute, BOTOX qualifies for the plasma-derived product exclusion because it is a "biological product that is derived from human whole blood or plasma" by virtue of its HSA content. AbbVie believes that this straightforward application of the statute should resolve this matter and result in BOTOX's exclusion from the Program.

- This conclusion aligns with CMS's statutory interpretation of "qualifying single source drug" (QSSD), which requires consideration of finished biological products in determining eligibility for the Program.

- Even if CMS adopted a new interpretation in which only active ingredients are considered under the plasma-derived product exclusion, BOTOX would qualify for the plasma-derived exclusion. HSA is active in BOTOX because of its critical role in enabling the effectiveness of onabotA.

- The manufacturing, supply, and regulatory complexities and risks underlying plasma-derived products that warrant their special status under the IRA also safeguard against manufacturers from adding HSA just to avoid Program selection. Excluding BOTOX does not pose a threat of changing eligibility for other biological products. Indeed, based on our research concerning approved products containing plasma-derived excipients, BOTOX is the only product that would be selection-eligible absent application of the plasma-derived exclusion.

I. BOTOX Is Exempt from the Program Under the Plain Text of the Plasma-Derived Product Exclusion.

Under a plain reading of the IRA's text, the presence of HSA in BOTOX triggers the plasma-derived product exclusion to the Program. CMS's authority to select drugs and biological products for inclusion in the Program is limited by the IRA's specific eligibility requirements. As

abbvie

relevant here, only a "qualifying single source drug" may qualify as a "negotiation-eligible drug" subject to selection under the Program. 42 U.S.C. § 1320f-1(d)(1). But the IRA expressly provides that "the term 'qualifying single source drug' does not include" certain excluded products. *Id.* § 1320f-1(e)(3). One such exclusion is for a "plasma-derived product[]," which the IRA defines as a "biological product that is derived from human whole blood or plasma." *Id.* § 1320f-1(e)(3)(C). This straightforward language indicates a sole requirement for the application of the plasma-derived product exclusion: namely, a biological product must be "derived from"—*i.e.*, "obtain[ed]" from—"human whole blood or plasma." *See, e.g.*, The New Oxford American Dictionary (2001).

BOTOX undoubtedly satisfies this test. HSA, a critical component of BOTOX, is "derived from" plasma collected from human donors. BOTOX in its finished dosage form includes HSA, and thus AbbVie's ability to market BOTOX depends on the presence of HSA. *See* 21 C.F.R. § 601.12. Likewise, BOTOX's approved product labeling states, "This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases . . . ." (USPI, Section 5.14). The presence of HSA thus renders BOTOX a plasma-derived product under the IRA, and CMS is thereby prohibited from selecting BOTOX as part of the Program.

"[W]hen the statute's language is plain," as it is here, it must be "enforce[d] . . . according to its terms." *Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) (internal quotation marks and citation omitted). Congress "says in a statute what it means and means in a statute what it says there." *Connecticut National Bank v. Germain*, 503 U.S. 249, 254 (1992). Accordingly, CMS may not override or add to Congress's decision that the plasma-derived product exclusion applies when a single condition is met; that is when a product is "derived from human whole blood or plasma." BOTOX unambiguously satisfies this requirement.

This plain-text interpretation is also consistent with CMS's limited guidance on the plasma-derived product exclusion, which has not changed since the Program was first implemented. In its final guidance for Initial Price Applicability Year (IPAY) 2028 of the Program, CMS briefly stated that "[f]or purposes of this exclusion, a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling." Memorandum, Center for Medicare & Medicaid, Department of Health & Human Services, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 (2025) (IPAY 2028 Final Guidance), at 173. The guidance goes on to say that CMS will rely on "product information available on the FDA Approved Blood Products website" and "databases such as FDALabel and the FDA Online Label Repository to verify if the product is derived from human

abbvie

whole blood or plasma."[1] *Id.* This guidance suggests that CMS views the plain text reading of the exclusion as we do. That is, a product's derivation from human whole blood or plasma satisfies the exclusion as gleaned from a product's approved labeling. Here, BOTOX's FDA-approved product labeling—as posted on the cited FDALabel and the FDA Online Label Repository websites—expressly states that BOTOX "contains albumin, a derivative of human blood." BOTOX USPI at Section 5.14. CMS's stated view in Guidance would thus include BOTOX under the exclusion.

II. Concluding that BOTOX Meets the Conditions for the Plasma-Derived Exclusion Aligns With CMS's Statutory Interpretation of QSSD.

The above conclusion based on the plain language of the statute is the only one that aligns with CMS's interpretation of QSSD since the enactment of the IRA, which requires consideration of the finished biological product.

As noted, the plasma-derived product exclusion is an exception from the statutory definition of QSSD. 42 U.S.C. § 1320f-1(e)(3)(C). CMS has interpreted QSSD to mean the bundle of all finished drug products sharing the same active ingredient(s) from the same applicant, including all dosage forms, *formulations*, and strengths of the product. IPAY 2028 Final Guidance, at 164; *see also id.* at 165 n.75 (noting that a potential QSSD "***means*** the specific constituent dosage forms and strengths (at the [National Drug Code] (NDC)-9 or NDC-11 level) that are identified as aggregated. . ") (emphasis added). CMS thus recognizes that a "biological product"—the phrase used in section 1320f-1(e)(3)(C)—is a finished dosage form that necessarily encompasses ingredients within the formulation.[2] Accordingly, because the BOTOX product contains the plasma-derived ingredient HSA, it meets the criteria for the plasma-derived exclusion based on CMS's statutory interpretation of QSSD.

[1] CMS does not provide any information regarding how it uses these FDA databases, including how it resolves conflicts between the different sources. As noted in previous communications, FDA's Approved Blood Products website, including the list of fractionated plasma products, should not be a definitive source to determine whether "a biological product is derived from human whole blood or plasma" under the IRA. *See, e.g.,* October 16 AbbVie Letter, at 8 n.32. For example, the list is far from a comprehensive catalog, and there appear to be products missing from the ledger despite labeling statements indicating that they are sourced from human plasma. *See, e.g.,* RhoGAM® Ultra-Filtered PLUS [Rho(D) Immune Globulin (Human)], BLA 103777, USPI at Section 11 (RhoGAM is "manufactured from human plasma containing anti-D from Rh-negative donors immunized with Rh-positive red blood cells"); KOĀTE [Antihemophilic Factor (Human)], BLA 101130, USPI at Section 11 ("KOĀTE is purified from the cold insoluble fraction of pooled human plasma"); PLASMANATE [Plasma Protein Fraction (Human)], BLA 101140, USPI at "Description" ("This product has been prepared from large pools of human plasma"). In any case, the fractionated plasma products website does list albumin as a fractionated plasma product.
[2] CMS has taken similar position in litigation. *See, e.g.,* October 16 AbbVie Letter, at 7 (discussing CMS's defense of its decision to aggregate insulin aspart products from Novo Nordisk).

abbvie

III. HSA Should Be Considered Active in BOTOX For Purposes of the Plasma-Derived Product Exclusion.

Even if CMS were to adopt a new interpretation of "biological product" by adding non-statutory language linking eligibility of the exclusion to biological products containing only plasma-derived active ingredients, BOTOX nevertheless should be excluded from selection for the Program because HSA is pharmacologically active in BOTOX.

As set forth in the October 16 AbbVie Letter, the HSA in BOTOX is plasma-derived and is a critical component in BOTOX.[3] The majority of the protein content in BOTOX is from HSA and, more importantly, HSA has biological activity that directly contributes to the therapeutic effect of BOTOX.

Scientific knowledge about HSA's therapeutic effects has emerged since 1989, when BOTOX became the first botulinum toxin approved globally. In 1989, due to limitations in analytical technology, HSA was hypothesized to act only as a surfactant. However, since then, continued research and innovation by AbbVie and the broader scientific community have greatly expanded our understanding of botulinum toxins, and advances in analytical tools and techniques have provided greater clarity on how complex molecules such as toxins exert their therapeutic effects. Scientific literature now shows that the biological effect of toxins is dependent on the HSA concentration.[4] For example, in at least one published report, no toxin activity was found in the absence of HSA.[5] AbbVie also conducted its own research using modern analytical tools to investigate the role of HSA and onabotA at the molecular level. These studies show that HSA results in a pronounced increase in toxin binding and potency as well as increased peak effect and duration of effect in muscles, illustrating that HSA is integral to the safety and efficacy of BOTOX.[6]

Thus, even though BOTOX's formulation and biological properties have stayed consistent since 1989, our understanding of how each component in BOTOX works to exert its therapeutic effect is clearer today. Advances in analytics validate what has always been true: ***that the HSA in BOTOX is a critical component and has biological activity that directly contributes to the therapeutic effect of BOTOX***. In other words, HSA is active and more than an inert component;

---

[3] *Id.* at 2 –5.
[4] *See generally* Letter from Andrew Pickett, Ph.D., to Office of the General Counsel (Dec. 5, 2025) (describing various studies).
[5] *Id.* at 3 (citing Bigalke, H., Wohlfarth, K., Irmer, A., & Dengler, R. (2001). *Botulinum A toxin: Dysport improvement of biological availability*. *Exp Neurol*, *168*(1), 162–170 at 164. https://doi.org/10.1006/exnr.2000.7583).
[6] *Id.* at 4 –6.

abbvie

CONTAINS COMMERCIALLY CONFIDENTIAL INFORMATION
NOT SUBJECT TO FOIA; PRE-DISCLOSURE NOTIFICATION REQUIRED

this plasma-derived ingredient has a direct impact on the biological activity of onabotA and is integral to the clinical function in BOTOX.

IV. Policy Considerations Also Support Applying the Plasma-Derived Exclusion to BOTOX.

Although HSA is not identified as an active ingredient in BOTOX labeling due to the state of science and FDA conventions over thirty years ago, HSA has always been a critical part of BOTOX, as discussed in AbbVie submissions and subsequent CMS and HHS meetings. Without HSA BOTOX does not work. Simply put, the safety and efficacy of onabotA cannot be disentangled from the contribution of HSA. As our manufacturing record demonstrates, the highly sensitive and extremely dynamic relationship between onabotA and HSA means that BOTOX is sensitive to the same supply vulnerabilities and strict manufacturing and regulatory requirements Congress had in mind when it enacted this exception.[7]

The unique manufacturing, regulatory, and supply complexities associated with plasma-derived products not only justify their special status under the IRA, but they also minimize the risk that manufacturers will engage in gamesmanship by randomly adding HSA to avoid selection for the Program (certainly, there is no evidence that AbbVie incorporated HSA into BOTOX for an improper reason; indeed, HSA has been part of BOTOX since its original approval decades before enactment of the IRA). Simply put, manufacturers would not add HSA to avoid Program selection due to the significant risks and burdens associated with adding a plasma-derived component. Extracting HSA from donated plasma is a multistep process that starts with collecting blood from healthy donors and separating plasma from other blood components increasing the inherent variability of the output. Since human-source materials carry risk of exposure to infectious agents, collected plasma is subjected to various purification methods, viral inactivation, and removal processes to further ensure safety and efficacy. *See* 21 C.F.R. Parts 606 and 640 (imposing enhanced regulatory products applicable to blood and blood products). Manufacturers of products with HSA must also address the potential for variable supply and take steps to manage potential shortages. [redacted] In addition, products containing plasma-derived ingredients must include labeling

[7] *See generally* Declaration of Martin Gastens, Ph.D., at 2 (Dec. 5, 2025) (explaining that BOTOX supply is at risk without an adequate supply of appropriately qualified HSA).
[8] *Id.* at 2.
[9] *Id.*

abbvie

statements that communicate warnings and precautions specific to human-derived ingredients. *See* 21 C.F.R. Part 606, Subpart G.

Excluding BOTOX will not enable broad, unjustified, utilization of the plasma-derived product exclusion. AbbVie's analyses indicate that BOTOX would be the ***only*** otherwise "negotiation eligible" product that would qualify for the plasma-derived product exclusion if CMS looked beyond the active ingredient, as listed in a biological product's labeling. Based on our review of publicly available information, HSA is the only type of blood- or plasma-derived ingredient present in FDA-approved products listed as an excipient in labeling. Our research indicates that there are approximately 110 marketed products that contain HSA. This number is reduced to 37 products when filtered to remove products where the labeling identifies the plasma-derived component as the active ingredient, duplicate products that are repackaged and/or approved under the same application, and products approved under a New Drug Application. Within the remaining cohort, BOTOX appears to be the ***only product*** that is not multisource or otherwise exempt under the orphan-drug or low-spend exclusions. For example, other toxin products containing blood- or plasma-derived excipients like MYOBLOC (rimabotulinumtoxinB), DYSPORT (abobotulinumtoxinA), XEOMIN (incobotulinumtoxinA), and JEUVEAU (prabotulinumtoxinA-xvfs) would all appear to be exempt under the low-spend exclusion.[10]

*****

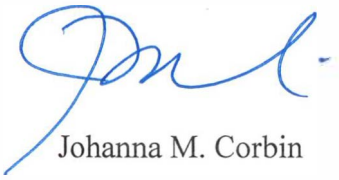
[10] The total estimated medicare spend includes Prescription Drug Event (PDE), Fee-for-Service (FFS) Part B Claims, and estimated Medicare Advantage sales during the IPAY 2028 drug selection period from November 2024 to October 2025.

abbvie

CONTAINS COMMERCIALLY CONFIDENTIAL INFORMATION
NOT SUBJECT TO FOIA; PRE-DISCLOSURE NOTIFICATION REQUIRED

We appreciate the steps that you and CMS have taken to date to understand the complex facts around BOTOX. We now ask that CMS complete its review and confirm that BOTOX meets the statutory criteria to be excluded from the Program. BOTOX easily qualifies under the plain text of the plasma-derived product exclusion. The evidence strongly supports this determination, and we are prepared to stand by our position.

Sincerely,



Johanna M. Corbin

EXHIBIT 3 to Mahmoud Declaration

CMS Newsroom

Press Releases Jan 27, 2026

CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program, Including First-Ever Part B Drugs

Administration Drug Prices

Share

CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program, Including First-Ever Part B Drugs

Negotiations Will Occur in 2026 With Negotiated Prices Effective in 2028

The Centers for Medicare & Medicaid Services (CMS) announced the selection of 15 high-cost prescription drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B for the third cycle of the Medicare Drug Price Negotiation Program. CMS also selected one previously negotiated drug for the program's first renegotiations. Negotiations with participating drug companies will occur in 2026 and any negotiated and renegotiated prices will become effective January 1, 2028.

Today's announcement builds on the Trump Administration's efforts to reduce prescription drug costs. In the second cycle of negotiations, Medicare reached agreement with participating manufacturers on all 15 selected drugs. Those prices will take effect January 1, 2027. If those new prices had been in effect in 2024, they would have saved an estimated $8.5 billion in net covered prescription drug costs (inclusive of Coverage Gap Discount Program Spending), which would have amounted to approximately 36% lower net spending in aggregate.

"For too long, seniors and taxpayers have paid the price for skyrocketing prescription drug costs," said CMS Administrator Dr. Mehmet Oz. "Under President Trump's leadership, CMS is taking strong action to target the most expensive drugs in Medicare, negotiate fair prices, and make sure the system works for patients — not special interests. This approach delivers real savings while strengthening accountability across the program."

Between November 2024 and October 2025, approximately 1.8 million people with Medicare Part D or Medicare Part B coverage used the 15 drugs selected for initial negotiation to treat a variety of conditions, including cancer, psoriatic arthritis, and human immunodeficiency virus type 1 infection. These drugs accounted for approximately $27 billion in total prescription drug spending under Medicare Part B and Part D, representing about 6 percent of total Part B and Part D spending.

CMS is also releasing a list of 50 top negotiation-eligible drugs based on combined expenditures under Medicare Parts B and D. The drugs selected for the third cycle represent the top 15 highest-spending drugs on this list.

"The publication of the list of top 50 negotiation-eligible drugs evidences CMS' commitment to transparency," said CMS Deputy Administrator and Director of Medicare Chris Klomp. "By applying clear eligibility criteria and practical negotiation policies, we are ensuring the program responds to market changes while delivering fairness and value for the American people."

The selected drug list for the third cycle of negotiations is:

- Anoro Ellipta
- Biktarvy
- Botox; Botox Cosmetic
- Cimzia
- Cosentyx
- Entyvio
- Erleada
- Kisqali

- Lenvima
- Orencia
- Rexulti
- Trulicity
- Verzenio
- Xeljanz; Xeljanz XR
- Xolair

The selected drug for renegotiation is:

- Tradjenta

All drugs were selected in accordance with the final guidance for the third cycle of negotiations, which incorporated refinements based on public feedback to increase the transparency of the Negotiation Program.

Drug companies with a selected drug for the third cycle of negotiations will have until February 28, 2026, to decide if they will participate in negotiations. In negotiations, CMS will consider the selected drug's clinical benefit, evidence about alternative treatments, the extent to which it addresses unmet medical needs, and its impact on specific populations, including people who rely on Medicare. CMS also considers other information, such as costs associated with research and development as well as current costs of production and distribution for selected drugs.

To review the fact sheet on the drugs selected for negotiation and renegotiation, visit: https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf

To review the fact sheet on the list of top 50 negotiation-eligible drugs, visit: https://www.cms.gov/files/document/factsheet-medicare-top-50-negotiation-eligible-drug-list-ipay-2028.pdf

For more information about the Medicare Drug Price Negotiation Program, visit: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program

EXHIBIT 4 to Mahmoud Declaration

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT

(hereinafter referred to as the "Agreement")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

ABBVIE INC.
(hereinafter referred to as the "Manufacturer")

For

BOTOX; BOTOX COSMETIC
(hereinafter referred to as the "Selected Drug")

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act ("the Act"), as set forth in the Inflation Reduction Act (IRA), Pub. L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the "Negotiation Program"), which sets forth a framework under which manufacturers and CMS may negotiate to determine a price (referred to as "maximum fair price" in the Act) for selected drugs in order for manufacturers to provide access to such price to maximum fair price eligible individuals; and

WHEREAS, CMS has designated the Manufacturer as the Primary Manufacturer, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act, of the Selected Drug, and CMS has included the Selected Drug on the list of selected drugs published on January 27, 2026; and

WHEREAS, the Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined price pursuant to section 1193 of the Act and in accordance with how the price is computed and applied across different strengths and dosage forms of the Selected Drug as identified by CMS and updated, as applicable, in accordance with sections 1194(f), 1195(b), and 1196(a)(2) of the Act and applicable guidance and regulations, including where the Selected Drug is sold or marketed by any Secondary Manufacturers as defined in applicable guidance or regulations;

NOW THEREFORE, CMS, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. Definitions

All terms included in this Agreement shall have the meaning given to them under the provisions of sections 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions, except where such terms are expressly defined in this Agreement.

II. CMS and Manufacturer Responsibilities

CMS shall administer the Negotiation Program and the Manufacturer agrees to comply with all applicable requirements and conditions for the Negotiation Program set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations implementing those provisions and any changes to the Act that affect the Negotiation Program.

Without limiting the foregoing, CMS and the Manufacturer agree:

a) During the negotiation period for the initial price applicability year for the Selected Drug, in accordance with section

1194 of the Act and applicable guidance and regulations CMS and the Manufacturer shall negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for the Selected Drug of the Manufacturer in order for the Manufacturer to provide access to such price—

i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during, subject to paragraph (b) of this section, the price applicability period; and

ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during, subject to paragraph (b) of this section, the price applicability period.

b) As applicable, CMS and the Manufacturer shall, in accordance with section 1194 of the Act and applicable guidance and regulations, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for the Selected Drug, in order for the Manufacturer to provide access to such maximum fair price (as so renegotiated)—

i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug; and

ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug.

c) Subject to paragraph (f) of this section and in accordance with applicable guidance and regulations, access to the maximum fair price (including as renegotiated pursuant to paragraph (b) of this section), with respect to such a Selected Drug, shall be provided by the Manufacturer to—

i. maximum fair price eligible individuals, who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act, at the pharmacy, mail order service, or other dispenser at the point-of-sale of the Selected Drug (and shall be provided by the Manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug), as described in paragraph (a)(i) or (b)(i) of this section, as applicable; and

ii. hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug, as described in paragraph (a)(ii) or (b)(ii) of this section, as applicable.

d) The Manufacturer shall submit to CMS, in a form and manner specified by CMS and in accordance with applicable guidance and regulations, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f) of the Act), and for section 1192(f) of the Act, with respect to the Selected Drug—

i. information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the Selected Drug for the applicable year or period;

ii. information that CMS requires to carry out the negotiation (or renegotiation) process under sections 1191 through 1198 of the Act; and

iii. information that CMS requires to carry out section 1192(f) of the Act, including rebates under section 1192(f)(4) of the Act.

e) The Manufacturer shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations.

f) Under this Agreement and in accordance with applicable guidance and regulations, the Manufacturer—

i. Shall not be required to provide access to the maximum fair price under paragraph (c), with respect to the Selected Drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at a covered entity described in section 340B(a)(4) of the Public Health Service

Act, to such covered entity if the Selected Drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

ii. Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for the Selected Drug.

g) In accordance with section 1193(c) of the Act and applicable guidance and regulations, information submitted to CMS under the Negotiation Program by the Manufacturer that is proprietary information of such Manufacturer, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States to carry out such Negotiation Program, unless otherwise required by law.

III. Effective Date, Term and Termination

a) This Agreement shall have an effective date of the date this Agreement is signed by both parties.
b) The term of this Agreement shall be from the effective date until the termination date, which shall be the earlier of the first day that the Selected Drug is no longer a selected drug pursuant to CMS' determination in accordance with section 1192(c) of the Act and applicable guidance and regulations, or the date that the Agreement is terminated by either party in accordance with applicable guidance and regulations.
c) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations.

IV. General Provisions

a) This Agreement contains the entire agreement of the parties with respect to the subject matter of this Agreement and supersedes all prior oral and written representations, agreements, and understandings of the parties. If CMS and the Manufacturer reach agreement on a price for the Selected Drug pursuant to section II(a) or II(b) of this Agreement, CMS and the Manufacturer shall execute an addendum setting forth the price for the Selected Drug that will apply for purposes of this Agreement.
b) CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement.
c) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement shall be sent by email. CMS shall provide the appropriate email address for notice in guidance, rulemaking, or other publications. The Manufacturer shall provide the appropriate email address(es) for notice to CMS in a form and manner specified by CMS.
d) Nothing in this Agreement shall prohibit the Manufacturer from transferring the Selected Drug and obligations of this Agreement to another entity in accordance with applicable guidance and regulations.
e) Nothing in this Agreement shall limit the Manufacturer from providing access under the Medicare program to a price lower than the price determined pursuant to this Agreement.
f) In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.
g) Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.
h) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.
i) This Agreement shall be construed in accordance with Federal law and any ambiguities shall be interpreted in the manner that best effectuates the statute. Any litigation relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court. Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations,

or guidance.

j) CMS and the Manufacturer acknowledge and agree that in accordance with section 1197 of the Act and 26 U.S.C. § 5000D, the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the requirements of the Negotiation Program, including violations of this Agreement.

k) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

V. Signatures

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

Date: 02/25/2026

Name: Dalia Mahmoud

Title: VP

P-Number: P1003

Manufacturer Address: 1 North Waukegan Road, North Chicago, Illinois 60064

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Date: 02/26/2026

Name: Christina Ritter, PhD

Title: Deputy Director
Center for Medicare

Signature: